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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,986	02/05/2004	Jenny Louie-Helm	3100-0003.10	7141

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REED INTELLECTUAL PROPERTY LAW GROUP
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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,986	LOUIE-HELM ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for reconsideration and remarks, all filed 06/13/05. Claims 1-26 are pending.

Claim Rejections - 35 USC § 102

1. The rejection of claims 1-6, 10 and 11 under 35 U.S.C. 102(b) as being anticipated by Mehra et al. (US 5,830,576) is withdrawn.

While a disintegration test is performed, while it is known in general that the release profile of dosage forms is predetermined when dosage forms are formulated and this is evidenced in the matrix polymers used with the active agents, a controlled release matrix or immediate release matrix and extended or delayed release matrix. Also, in general, since in vitro test analysis correlate in vivo pattern of drug release, it would be obvious to select dosage form that correlates most closely with the in vitro test analysis, and thus closely with the desired release pattern after the test. However, since Mehra does not explicitly disclose selecting the dosage form having predetermined in vitro drug release profile for administering to a patient, this rejection is withdrawn. Therefore, applicants' argument with respect to claims 1-6, 10 and 11 is persuasive.

2. The rejection of claims 17 and 25 under 35 U.S.C. 102(b) as being anticipated by Mehra et al. (US 5,830,576) is withdrawn because Mehra does not disclose administering the pharmaceutical with food. However, regarding applicants statement of contemplating human patient, it is respectfully noted that the claims have not recited human patient and limitations form the specification cannot be read into the claims.

3. Claims 1-8, 10-13, 17, 18 and 26 remain rejected under 35 U.S.C. 102(b) as being anticipated by Franz et al. (US 5,232,704).

Applicants argue that the disintegration test at column 9, lines 7-30, does not suggest disintegration test as being used to test the in vitro drug release profile of the active agent in the dosage form but Franz uses the disintegration test solely to determine; and that Franz does not discuss how much active agent is released during erosion using disintegration. Applicants further state in column 21, lines 32-56, Franz clearly discloses dissolution test to determine the release profile of the active agent from the sustained release dosage form. Finally, applicants state that the rejection should be withdrawn because, Franz does not teach or suggest that the disintegration test is used to correlate in vitro and in vivo drug release profiles of the active agent.

4. Applicants' arguments filed 06/13/05 have been fully considered but they are not persuasive.

Regarding the amount of active agent released or not released during the erosion using the disintegration test, it is respectfully noted that the instant claims do not recite the amount of active agents released in the disintegration test and by this argument, applicants are arguing limitations not recited in the claims. Regarding disintegration test, it is noted that in column 9, lines 7-21, Franz specifically discloses designing an *in vivo* prolonged gastric retention dosage form based on selecting a "bi-layer capsule having displayed adequate *in vitro* properties." Thus in this section Franz correlate the *in vitro* release properties with the desired *in vivo* release. Franz uses the USP disintegration test. Regarding column 21, lines 32-56, Examiner agrees with applicants that in that section Franz describes USP dissolution test, not disintegration test

and in line 55 state that no significant disintegration was observed; thus this section looks at dissolution while column 9, line 9 looks at disintegration test and correlates *in vitro* with *in vivo* release profiles.

Claim Rejections - 35 USC § 103

5. Claims 1-26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Shell et al. (US 5,972,389) in view of applicants' admitted prior art.

Applicants argue that paragraph 0005 makes specific mention stating that disintegration test described therein should not be used immediate release dosage forms; and that according to the state of the art, dissolution test and not disintegration test was used to test release profiles in controlled release dosage forms; that disintegration test has closer correlation to the in vivo and in vitro active releases.

6. Applicants' arguments filed 06/13/05 have been fully considered but they are not persuasive.

It is noted that paragraph 0005 states "for immediate release dosage forms, an **additional test that is conventionally used to supplement dissolution as a predictor of the in vivo release profile is the USP Disintegration Test**," and not that disintegration test is not to be used with immediate release dosage forms. Specifically, disintegration test is used to supplement dissolution test in immediate release dosage forms. There is no mention that modified release dosage form is equivalent to controlled release dosage form. The unusual results of the disintegration over dissolution is not made and it is not Examiner's opinion that disintegration test would supplement dissolution test, but rather paragraph 0005 of applicants' specification.

It is also noted that the prior art as well as the claimed invention discloses controlled release dosage form.

Suggestion for restriction, not unity of invention

Restriction would have been proper because the method of the instant claims, that is, administering a sustained release dosage form can also be practiced with another dosage form. However, Examined took on the burden for searching the inventions. Since applicants do not agree, the restriction is not made.

Double Patenting

7. Claims 1-3 remain provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 49-51 of copending Application No. 10/281,284. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Applicants state that the double patenting rejection should be dropped because none of the applications have been issued.

8. Applicants' arguments filed 06/13/05 have been fully considered but they are not persuasive.

The rejection will continue to be made until the claims are amended to overcome the rejection.

9. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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